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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/912,951	08/14/1997	THOMAS R. CECH	07681.0006	5206

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GERON CORPORATION
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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

21

DATE MAILED: 11/27/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/912,951

Applicant(s)

CECH ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 27 August 2001 is acknowledged. Claims 46-81 are cancelled by Applicant's amendment. New claims 83-90 are pending in this application.
2. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

3. The rejection of claims 46-57 and 60-66 under 35 U.S.C. 112, first paragraph, is withdrawn in response to Applicant's cancellation of these claims.
4. The rejection of claims 67-70 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's cancellation of these claims.
5. The rejection of claims 67, 69, and 70 under 35 U.S.C. 102 is withdrawn in response to Applicant's cancellation of these claims.
6. The objection to claims 71-81 as depending from a rejected claim is withdrawn in response to Applicant's cancellation of these claims.

New Grounds of Rejection/Objection

7. Claims 83-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has described the polynucleotide sequence of SEQ ID NO: 1 and presented hTRT motifs. However, the new claims are drawn to cells containing recombinant

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polynucleotides identified by hybridization to the complement of SEQ ID NO:224, which is 20 nucleotides in length.

MPEP 2163 states:

Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

and

A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement. See *Gentry Gallery*, 134 F.3d at 1480, 45 USPQ2d at 1503; *In re Sus*, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962)

and

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

While SEQ ID NO: 224 is present in the application as filed, there are no teachings in the specification to indicate that sequences comprising it constitute Applicant's invention. There is no indication in the specification as filed that SEQ ID NO: 224 is an essential or distinguishing characteristic of hTERT; it is not described as a conserved sequence or one encoding a region necessary for function. Sequences set forth by Applicant as critical for function, such as motifs important for function, are omitted from the new claims. In addition, as stated above, SEQ ID NO:224 is only 20 nucleotides in length. The claims thus encompass polynucleotides that vary substantially in length and also in composition from that which is disclosed by Applicant. The

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disclosed by Applicant. The instant disclosure of one nucleic acid thus does not adequately describe the scope of the claimed genus. There are no teachings in the specification to indicate that SEQ ID NO:224 is of any significance in the structure and function of hTERT, and thus no teachings to indicate that sequences comprising it would have the required structural and functional features of the claimed molecules. Applicant's teachings indicate that important features lie elsewhere in the disclosed full-length sequence. Thus one of skill in the art would not conclude, based on Applicant's disclosure, that Applicant was in possession of the claimed invention, that is, sequences comprising SEQ ID NO: 224 and having hTERT activity.

8. Claims 83-90 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO:1, does not reasonably provide enablement for sequences comprising SEQ ID NO: 224. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As stated above, SEQ ID NO: 224 is 20 nucleotides in length and, based on Applicant's disclosure, does not encompass the essential features of sequences encoding functional hTERT molecules. Thus sequences comprising it would have very different structures and characteristics, and Applicant's teachings of certain regions important for function of hTERT is not sufficient to enable to invention as broadly claimed.

In *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), the Courts have held that:

Inventor should be allowed to dominate further patentable inventions of others where those inventions were based in some way on his teachings, since some improvements, while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to scope of

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enablement provided by specifications to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with the degree of unpredictability of factors involved." (emphasis added)

MPEP §2164.08 teaches that:

"The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984)"

And further:

[C]laims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

Applicant's disclosure of certain characteristics of one molecule which are important for its function is not adequate guidance to allow one of skill to predict which sequences comprising a sequence not described as essential would have same claimed function. The motifs set forth are limited in their homology to other sequences; considerable variation among the sequences set forth in Figure 4 is observed. One of skill would, based on Applicant's teaching, be able to predict only a few regions important for function and would be able to identify only a few conserved amino acid residues. One of skill would thus not be able to predict what changes from SEQ ID NO:1, in what regions, would allow for preservation of function and what changes would result in a loss of the claimed activity. As stated in the previous office action, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining

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similar activity is unpredictable. Thus, since there are a large number of molecules potentially within the scope of the claims, and the ability to identify those with the claimed function is not, based on Applicant's disclosure, predictable, it would require undue experimentation for the make and use the invention as broadly claimed.

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.